

REMARKS

Specification Amendments

The title and abstract of the instant specification have been amended to be descriptive of the instant invention as requested by the Examiner. No new matter is introduced.

Claim Status

Claim 59 has been amended to recite a single cell.

Claim 60 has been amended to indicate that the claimed progeny comprise the functional genetic element.

Claim 61 has been amended to recite a single seed as well as to indicate that the claimed seed comprises the functional genetic element.

Claim 62 has been amended to indicate that the promoter is operatively linked to the gene encoding CryET29.

Claims 71-72 have been added. Support for these new claims is found on page 7, lines 3-12 and page 70, lines 12-14 of the instant specification.

With the present amendments, there are now 7 claims pending, namely claims 57, 59-62 and 71-72. Pursuant to 37 C.F.R. §1.118(a), Applicants respectfully submit that the foregoing amendments do not introduce any new material into the application.

Objections to the Specification

The abstract and the title were objected to for allegedly not being descriptive of the instant invention. In response, Applicants have amended the abstract and title to be descriptive of the instant invention as claimed.

Objections to the Sequence listing

The sequence listing is objected to under 35 U.S.C.132 (a) as allegedly introducing new matter into the disclosure of the invention. Applicants respectfully traverse this objection.

The Examiner states that the corrected sequence listing introduces new matter into the disclosure. Applicants disagree.

The question being asked here is whether biological deposits inherently disclose the sequences. According to a recent Federal Circuit decision a reference in the specification to a deposit in a public depository, which makes its contents accessible to the public, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement. *See Enzo Biochem Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002). The decision states:

“We therefore agree with Enzo that reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement.” *Id.* at 966.

Just like in *Enzo Biochem*, Applicants deposited the subject nucleotide sequence in the form of a recombinant DNA molecule within bacterial host strains. There is no doubt that

Applicants have the possession of the claimed invention. The reference to the deposits inherently describes and encompasses the same scope as the corrected nucleotide sequence as set forth in SEQ ID NO:1 with the correction at the positions of 385-386 and the corrected protein sequence as set forth in SEQ ID NO:2 with the correction at the position of 129. The deposits inherently have the possession of the corrected sequences.

Applicants have shown that the written description requirement is met by disclosure of nearly complete structure in the originally submitted sequence listing and drawings, i.e., >99% of a *cryET29* gene sequence with errors at only 2 positions out of 691 nucleotides and >99% of a CryET29 protein sequence with only one error at 1 position out of 231 amino acids. Applicants have also provided extensive written descriptions on evaluating the plasmids contained in the deposited bacterial strains, wherein the plasmids contain the subject nucleotide sequence, as well as evaluating the subject protein expressed in the deposited bacterial strains. *See* Examples 1-7 of the instant specification.

With the deposits referenced and sufficient guidance provided in the instant specification, a person of skill in the art, reading the accession numbers referenced, can readily obtain the corrected sequences by following the guidance to excise the nucleotide sequence from the deposited bacterial strain containing the sequence. Consequently, Applicants assert that the inadvertent sequence errors occurred in the originally filed sequence listing and drawings are purely “typographic” errors and that the sequence corrections being made are supported by the original disclosure by way of the biological deposits.

Applicants further point out that declaration of inventor Donovan regarding sequencing corrections along with the deposit receipt for *Escherichia coli* strain EG11513 having NRRL accession number of NRRL B-21624 was previously submitted to the Examiner. However, there

is no acknowledgment that the Examiner considered the declaration and/or deposit in this latest Office Action. Applicants herewith re-submit the declaration and deposit receipt for *Escherichia coli* strain EG11513 in Exhibit A as well as submit deposit receipt of *Bacillus thuringiensis* strain EG4096 having NRRL accession number of NRRL B-21582 in Exhibit B, which was previously submitted in the great-grandparent application Serial No. 08/721,259. These deposits were made prior to the earliest filing date of the present application and are representative of the original disclosure.

As presented previously, Applicants had re-sequenced the *cryET29* gene contained in the recombinant plasmid pEG1298, which is contained in the deposited *Escherichia coli* strain EG11513 (NRRL B-21624), and found it to contain two differences from the nucleotide sequence listing shown in SEQ ID NO:1 and in FIG. 1B of the great-grandparent (Serial No. 08/721,259) and grandparent (Serial No. 09/611,216) applications of the present case. These differences are a guanine or “G” at position 385, and a cytosine or “C” at position 386. These nucleotides were reported in the original sequence listing to be a cytosine or “C” at position 385 and a guanine or “G” at position 386. These nucleotide changes from “CG” to “GC” at positions 385-386, result in a corresponding amino acid change at position 129 from an Arginine (Arg) to an Alanine (Ala).

The herewith re-submitted Donovan’s declaration along with the deposit receipts for *Bacillus thuringiensis* strain EG4096 having the accession number of NRRL B-21582 and *Escherichia coli* strain EG11513 having the accession number of NRRL B-21624 is in support of the above-described sequence corrections. Specifically, Applicants assert that this sequencing error was inadvertent and that the corrections do not constitute new matter since the original deposits were made relating to the present case on May 30, 1996 and September 12, 1996,

respectively, both of which dates are prior to the earliest filing date of the present application. *Bacillus thuringiensis* strain EG 4096 was the strain from which CryET29 was originally isolated, and *Escherichia coli* strain EG11513 contains a plasmid on which the gene encoding CryET29 was cloned. Since the gene encoding CryET29 was present in these deposited samples, anyone of skill in the art could have sequenced this gene and identified the correct sequence containing the “GC” nucleotides at positions 385 and 386.

Applicants note that the same sequence corrections have been approved by Examiner Prouty and made of record in the parent application (Serial No. 10/386,972) of the present case.

In view of the above remarks and supporting documents submitted herewith (i.e. declaration and deposit receipts), Applicants respectfully request that the Examiner reconsider this objection regarding the sequence listing.

The Examiner further states that Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120. Applicants respectfully disagree.

As discussed above, the subject sequence corrections in the sequence listing and FIG. 1B do not introduce a new matter to the original disclosure. The above deposit receipts are representative of the original disclosure. Simply correcting sequencing errors does not change the fact that the transgene and corresponding crystal protein remain the same in the disclosure of the invention both in the parent application and in the later-filed applications. Consequently, Applicants assert that the present application is entitled to receive the benefit of the earliest filing date under 35 U.S.C. 120.

New Claims

Applicants have added two new claims, of which claim 71 is directed to a transgenic plant comprising a *cryET29* transgene as contained in plasmid pEG1298 which is contained in *Escherichia coli* strain having accession number NRRL B-21624, and claim 72 is directed to a transgenic plant comprising a transgene encoding a CryET29 crystal protein as produced in *Bacillus thuringiensis* strain having accession number NRRL B-21582. Direct support for these new claims is found on page 7, lines 3-12 and page 70, lines 12-14 of the instant specification.

Applicants submit that new claim 71 encompasses the same scope as the corrected SEQ ID NO:1, and that new claim 72 encompasses the same scope as the corrected SEQ ID NO:2.

Claim Rejection – 35 USC § 112, Second Paragraph

Claims 59-62 stand rejected under 35 USC § 112, second paragraph, as allegedly being indefinite. In response, Applicants have amended claims 59-62 to address the issues raised by the Examiner. Upon entry of the present amendments, this rejection is overcome.

This document is filed timely. No fee is believed to be due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is authorized to deduct said fees from Howrey LLP Deposit Account No. 01-2508/11792.0017.DVUS03.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Wendy Davis".

J. Wendy Davis, Ph.D.

Reg. No. 46,393

Agent for Assignee

MONSANTO TECHNOLOGY LLC

Customer No. 45607
HOWREY LLP
1111 Louisiana, 25th Floor
Houston, Texas 77002
(713) 787-1400

Date: November 4, 2005



CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the U.S. Patent and Trademark Office at 703-746-5335 on the date below:

9-25-03

Date

Amy G. Klann

AMY G. KLANN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mark J. Rupar
William P. Donovan
Yuping Tan
Annette C. Slaney

Group Art Unit: 1652

Examiner: R. Prouty

Serial No.: 10/386,972

Atty. Dkt. No.: MECO:017--2
11792.0017.DVUS02

Filed: March 12, 2003

For: BACILLUS THURINGIENSIS CRYET29
COMPOSITIONS TOXIC TO
COLEOPTERAN INSECTS AND
CTENOCEPHALIDES SPP.

DECLARATION REGARDING DNA SEQUENCING CORRECTIONS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, William P. Donovan, hereby declare that:

1. The cryET29 gene contained on recombinant plasmids pEG1298 and pEG1299 was recently re-sequenced at Monsanto, and has been found to contain two differences from the DNA sequence listed in the above-referenced application as SEQ ID NO:1 and in Fig. 1B. I became aware of these two differences in data recently furnished to me. The differences are found in SEQ ID NO:1 and correspondingly in Fig. 1B, where the nucleotide at position 385 should be listed as a guanine residue instead of a cytosine, and the nucleotide at position 386 should be listed as a cytosine residue instead of a guanine. These two nucleotide changes result in a corresponding

BEST AVAILABLE COPY

change in the amino acid sequence at position 129 from an arginine residue (Arg) to an alanine residue (Ala) in SEQ ID NO:1, SEQ ID NO:2, and in Fig. 1B.

2. The *Bacillus thuringiensis* strain from which CryET29 was originally isolated (EG4096) as well as *Escherichia coli* strain EG11513 containing plasmid pEG1298 with the gene coding for CryET29, were deposited with the Agricultural Research Culture Collection on May 30, 1996 and September 12, 1996, respectively. The date of the deposit was before the U.S. filing date of this application. Copies of the microorganism deposit receipts have been submitted with this application.

3. Since the gene encoding CryET29 was present in deposited samples EG4096 and EG11513, anyone of skill in the art could have sequenced this gene and identified the correct sequence containing the "GC" nucleotides at positions 385 and 386.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

William P. Donovan
William P. Donovan, Ph.D., Inventor

Date: September 22, 2003

Monsanto Company
700 Chesterfield Parkway North
Chesterfield, Missouri 63198

BEST AVAILABLE COPY

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSE OF PATENT PROCEDURES

INTERNATIONAL FORM

Mr. Mark Rupar
Ecogen, Inc.
1005 Cabot Blvd. West
Langhorne, PA 19047

NAME AND ADDRESS
OF DEPOSITOR

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the
DEPOSITOR:

Escherichia coli
EG11513

Accession number given by the
INTERNATIONAL DEPOSITARY AUTHORITY:

NRRL B-21624

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I. above was accompanied by:

- ☐ a scientific description
☒ a proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I.
above, which was received by it on September 12, 1996 (date of the original deposit)¹

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I. above was received by this International
Depositary Authority on (date of the original deposit) and
a request to convert the original deposit to a deposit under the Budapest Treaty
was received by it on (date of receipt of request for conversion)

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Agricultural Research Culture
Collection (NRRL)
International Depositary Authority
Address: 1815 N. University Street
Peoria, Illinois 61604 U.S.A.

Signature(s) of person(s) having the power
to represent the International Depositary
Authority or of authorized official(s):

Date: 9-15-96

Where Rule 6.4(d) applies, such date is the date the depositary authority was acquired.

BEST AVAILABLE COPY

| CERTIFICATE OF MAILING | |
|---|---------------------------------------|
| 37 C.F.R. 1.8 | |
| I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date below: | |
| <i>Feb. 19, 2005</i> Date | <i>Paula S. Lundhart</i> Signature |

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mark J. Rupar
William P. Donovan
Yuping Tan
Annette C. Slaney

Group Art Unit: 1652

Examiner: R. Prouty

Serial No.: 09/611,216

Atty. Dkt. No.: MECO:017--1
11792.0017.DVUS00

Filed: July 6, 2000

For: BACILLUS THURINGIENSIS CRYET29
COMPOSITIONS TOXIC TO
COLEOPTERAN INSECTS AND
CTENOCEPHALIDES SPP.

DECLARATION OF BIOLOGICAL CULTURE DEPOSIT

Commissioner for Patents
Washington, D.C. 20231

Sir:

I, William P. Donovan, hereby declare that:

1. The following materials referred to in the specification of the above-referenced application have been deposited with the Agricultural Research Culture Collection.

BEST AVAILABLE COPY

TAXONOMIC DESCRIPTION

DEPOSIT NUMBER

EG11513

NRRL B-21624

2. The date of the above deposit is on or before the U.S. filing date of this application.
3. The name and address of the depository is:

Agricultural Research Culture Collection (NRRL)
International Depositary Authority
1815 N. University Street
Peoria, Illinois 61604
4. With respect to the permanence of the culture deposit:
 - a. the depository is an official depository in accordance with the Budapest Treaty for the above deposited cultures;
 - b. the depository affords permanence of the deposit for at least 30 years or at least 5 years after the most recent storage request, whichever is longest; and
 - c. evidence that permanent availability of the microorganism is assured as provided in the form of the attached copy of the contract with the above-mentioned depository with respect to the deposited cultures.

I affirm that should the microorganisms mutate, become nonviable or be inadvertently destroyed, I will replace such microorganisms for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, plus six (6) years to cover the statute of limitations, whichever period is longer.

BEST AVAILABLE COPY

5. With respect to availability of the cultures I affirm that the deposit has been made under conditions of assurance that during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request; and all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

William P. Donovan
William P. Donovan, Ph.D., Inventor

Date: January 15, 2002

Monsanto Company
700 Chesterfield Parkway North
Chesterfield, Missouri 63198

BEST AVAILABLE COPY

CERTIFICATE OF MAILING
37 C.F.R 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on the date below:

July 14, 1999 *Jeannette Goldsberry*
Date ~~Jeannette Goldsberry~~ Jeannette Goldsberry

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Mark J. Rupar
William P. Donovan
Yuping Tan
Annette C. Slaney

Group Art Unit: 1652

Examiner: R. Prouty

Serial No.: 08/721,259

Atty. Dkt. No.: MECO:017/KAM

Filed: September 26, 1996

For: BACILLUS THURINGIENSIS CRYET29
COMPOSITIONS TOXIC TO
COLEOPTERAN INSECTS AND
CTENOCEPHALIDES SPP.

DECLARATION OF BIOLOGICAL CULTURE DEPOSIT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, William P. Donovan, hereby declare that:

1. The following materials referred to in the specification of the above-referenced application have been deposited with the Agricultural Research Culture Collection.

TAXONOMIC DESCRIPTION

DEPOSIT NUMBER

EG4096

NRRL B-21582

EG11494

NRRL B-21583

2. The date of the above deposit is on or before the U.S. filing date of this application.
3. The name and address of the depository is:

Agricultural Research Culture Collection (NRRL)
International Depositary Authority
1815 N. University Street
Peoria, Illinois 61604
4. With respect to the permanence of the culture deposit:
 - a. the depository is an official depository in accordance with the Budapest Treaty for the above deposited cultures;
 - b. the depository affords permanence of the deposit for at least 30 years or at least 5 years after the most recent storage request, whichever is longest; and
 - c. evidence that permanent availability of the micro organism is assured is provided in the form of the attached copy of the contract with the above-mentioned depository with respect to the deposited cultures.

I affirm that should the microorganisms mutate, become nonviable or be inadvertently destroyed, I will replace such microorganisms for at least 30 years from the date of the original deposit, or at least 5 years from the date of the most recent request for release of a sample or for the life of any patent issued on the above-mentioned application, plus six (6) years to cover the statute of limitations, whichever period is longer.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

William P. Donovan
William P. Donovan, Ph.D., Inventor

Date: July 7, 1999

Ecogen, Inc.
2005 Cabot Boulevard West
Langhorne, PA 19047-1810

INTERNATIONAL FORM

TO
Ecogen Inc.
Attn: Dr. Mark Rugar
2005 Cabot Boulevard West
Langhorne, PA 19047-1810

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT
issued pursuant to Rule 7.1 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the
DEPOSITOR:

Bacillus thuringiensis
EG 4096

Accession number given by the
INTERNATIONAL DEPOSITARY AUTHORITY:

NRRL B-21582

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I. above was accompanied by:

- ☐ a scientific description
☒ a proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I.
above, which was received by it on May 30, 1996 (date of the original deposit)¹

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I. above was received by this International
Depositary Authority on (date of the original deposit) and
a request to convert the original deposit to a deposit under the Budapest Treaty
was received by it on (date of receipt of request for conversion)

V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Agricultural Research Culture
Collection (NRRL)
International Depositary Authority
Address: 1815 N. University Street
Peoria, Illinois 61604 U.S.A.

Signature(s) of person(s) having the power
to represent the International Depositary
Authority or of authorized official(s):

Date:

J. L. Sings
6-10-96

¹ Where Rule 6.4(d) applies, such date is the date on which the status of international
depositary authority was acquired.